



USG-Health Industry Partnership Program (UHIPP)

**Final Report
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U.S. Department of Commerce
International Trade Administration
Trade Development
Office of Microelectronics, Medical
Equipment and Instrumentation



The Office of Microelectronics, Medical Equipment and Instrumentation (OMMI) expresses its appreciation of the U.S. Agency for International Development (USAID) for partnering with them to help revitalize healthcare and reduce trade barriers in Russia and the Newly Independent States (NIS). The USG-Health Industry Partnership Program (UHIPP) provided revitalization efforts at a critical time in history. It was an exciting collaboration between U.S. government and industry to improve access to healthcare for the citizens of this region.

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Preface

The following report outlines the goals and achievements of the UHIPP program. The goals were lofty and the achievements many, and the work has really only just begun.

In May 1992, the U.S. Department of Commerce (DOC) and the U.S. Agency for International Development (USAID) partnered at a critical time in history. Russia and the NIS faced significant challenges in its delivery of healthcare to its citizens as it carved out an economy and a pathway to capitalism. While Russia and the NIS faced challenges, U.S. manufacturers of medical equipment and pharmaceuticals faced opportunities to enter a potentially vast market, desperately in need of their product. How might the U.S. government work toward its policy goals of assisting the growth of these economies through their infancy, and ensuring the improvement of the healthcare of the people? And how might U.S. industry play a role in entering risky and infant markets, harnessing the power of capitalism to help drive these new economies along? By partnering.

The USG-Health Industry Partnership Program (UHIPP) was that partnership. USAID knew that Russia and the NIS needed access to healthcare, and they knew that U.S. firms could provide that access. The risk expected of U.S. firms however would be just too great for them to use a purely market-driven investment strategy. Could U.S. firms be expected to make rational decisions about entering a market where the population did not know how to buy or sell, had no regulatory environment or if so, a different one than the day before? The UHIPP program allowed USAID to create an environment for U.S. industry through the efforts of DOC to minimize the expense and risk for U.S. firms to explore these important emerging markets. The UHIPP program also enabled DOC to work hand in hand with these new governments to open markets, reduce trade barriers, improve transparency, and advocate on behalf of U.S. firms.

The following report outlines what accomplishments were made during the six year UHIPP program, and it closes with a look to where we should go from here.

Executive Summary

“Rarely have I seen as ambitious and targetted a cooperative venture between the U.S. government and private industry as the USAID UHIPP program. This was an important first step and more like it must be taken.”

Ellis Mottur, Deputy Assistant Secretary, U.S. Department of Commerce

The USAID, USDOC, and U.S. industry partnered under the USG-Health Industry Partnership Program (UHIPP) to help revitalize healthcare and reduce trade barriers in Russia and the Newly Independent States (NIS). USAID would supply a fund, USDOC would administer that fund, and U.S. industry would use the opportunities provided by the fund to explore those new markets in desperate need for medical products.

From May 1992 to September 1994, USAID provided \$729,000 to DOC through an Interagency Agreement with three amendments:

May 15, 1992 - Original Award - \$208,000

July 13, 1993 - Amendment One - \$221,000

September 30, 1994 - Amendment Two - \$300,000

Total AID UHIPP Funding = \$729,000.

DOC organized the following health industries trade promotion events funded in large part by UHIPP funding:

Trade Mission to Moscow and Tatarstan, October 1992

Conference on Selling Used and Remanufactured Medical Equipment to NIS, Charleston, South Carolina, January 1993

Reverse Trade Mission and Conference on Selling Medical Products to Russia, San Diego, February 1993

Trade Mission to Ukraine, June 1993

St. Petersburg Medical Device Delegation Attendance at MedTrade Exhibition, Atlanta, November 1993

Ukraine Reverse Trade Mission and Conference, Chicago, March 1994

Trade Mission to the Urals Region, October 1994

Reverse Trade Mission - Biotechnology, Boston and San Francisco, November 1994

Trade Mission to Central Asia (Kazakhstan and Uzbekistan), June 1995

Ukraine Reverse Trade Mission to attend Medical Design and Manufacturing Trade Show, New York, June 1995

Trade Mission to the Russian Far East, October 1995

Russian Far East Reverse Trade Mission and Conference, Seattle, April 1996

Trade Mission to St. Petersburg and Siberia, September 1996

Russian Delegation Attendance at Greater New York Dental Show, New York City, November 1996

Trade Mission to Nizhny Novgorod and Tatarstan, October 1997

Reverse Trade Mission, Conference and Regulatory Roundtable, Los Angeles, February 1998

DOC also met numerous times on a formal and productive basis with the Russian government through the U.S.-Russia Business Development Committee's Health Industries Subgroup forum.

Neither the U.S. government nor private industry expected the UHIPP program to result in large export sales. These were economies just beginning to learn how to buy or sell, lacking adequate resources yet to make large purchases, and having institutional barriers to importing.

And neither did the U.S. government nor private industry expect to make great strides within the Russian government to create a business or regulatory environment inviting and hospitable to U.S. firms in a few short years.

Yet on both accounts, the UHIPP program produced unexpectedly successful outcomes in both areas. These successful outcomes are demonstrated in the following pages.

In recent months, Russia experienced a complete financial collapse. Future trade promotion activities are now sidelined for an indefinite period while the country manages its economy, and creates a business atmosphere attractive again to U.S. firms.

USAID UHIPP Accomplishments

There were just three goals of the UHIPP program: *provide market intelligence*, *encourage market penetration*, and *effect trade policy improvements* on behalf of U.S. industry. The chart outlines how each goal was met.

UHIPP Goal	Goal Achievement
Market Intelligence ¹	<ul style="list-style-type: none">• Trade Missions• Reverse Trade Missions• Conferences• Regulatory Roundtables• Medical Device Brochure
Market Penetration and Expansion ²	<ul style="list-style-type: none">• Trade Missions• Reverse Trade Missions• Reduction of Trade Barriers• Medical Device Brochure• Pharmaceutical MOU
Trade Policy ³	<ul style="list-style-type: none">• GCC Health Committee• Ad Hoc Work Group for Trade and Investment• U.S.-Russia Business Development Committee Health Industries Subcommittee• Committee for Trade and Investment (U.S.-Ukraine)• Medical Device Brochure• Pharmaceutical MOU• Pending Statement of Intent with Ukraine• Regulatory Roundtables

How We Did It

“There is no doubt that at this point in history, the partnership

between USAID, Commerce and private industry is key to the successful market emergence of the NIS.”

Jeffrey Gren, Director, Office of Microelectronics, Medical Equipment and Instrumentation, U.S. Department of Commerce

As was demonstrated, every goal of the UHIPP program was met or exceeded. The U.S. Department of Commerce used a variety of tools for accomplishing the USAID UHIPP goals of expanding these markets, reducing barriers to trade, and giving U.S. firms an opportunity to investigate the market with much less risk:

- A. Trade Missions
- B. Reverse Trade Missions
- C. Regulatory Roundtables
- D. Business Development Committee (BDC) Meetings/Activities
- E. Ad Hoc Work Group Meetings

A. Trade Missions

Business development trade missions to Russia and other NIS countries were sponsored by USAID and DOC under the UHIPP program. Missions were designed for U.S. companies offering medical equipment and supplies, dental products, pharmaceuticals, and healthcare services to identify and pursue commercial opportunities in the healthcare markets in Russia and other NIS countries. Mission itinerary included meetings with health officials and hospital administrators, customized one-on-one business appointments, site visits to hospitals and medical centers, special invitation receptions, and other events. Through these activities, U.S. company representatives met with healthcare end users (e.g. hospital and clinic directors), enterprise leaders, potential customers, distributors, joint venture partners, Russian Ministry of Health (MOH) officials and other local government officials, and members of the local healthcare community. The business opportunities realized on these missions included market exposure, direct sales, distributorships, management consulting, licensing agreements, and joint ventures.

Participation fees for U.S. medical industry firms to attend these missions were minimized thanks to the UHIPP funding. These missions allowed U.S. firms direct access to the emerging markets in Russia and the NIS at

relatively low cost which otherwise would be too expensive for U.S. small and medium sized enterprises (SMEs). The low participation fee was a significant selling point to encourage U.S. firms to participate.

Trade missions require a tremendous amount of time and effort to ensure a successful event. The following are the general steps necessary to make a trade mission a reality.

1. *Conduct market research and analysis* to pinpoint areas of interest for firms.
2. *Work closely with Foreign Commercial Service posts* for input, clearance.
3. *Determine a cost structure and logistics for the mission*, using factors such as transportation links, amount of time spent at the city, mission objectives, printing costs, translation costs, etc.
4. *Make the logistical arrangements*, including arranging for in-country airlines, hotels, ground transportation, interpreters, etc.
5. *Develop a mission announcement letter* for a national mailing.
6. *Develop a mission application kit*, outlining participants' duties and responsibilities, visa information, and other appropriate information.
7. *Organize incoming information*, such as requests, checks, marketing data forms, and mission directory profiles.
8. *Coordinate visa processing*.
9. *Develop mission brochure*, including information on mission participants and their companies, U.S. government officials in attendance, Russian attendees, and mission objectives.
10. *Develop mission briefing book*, with talking points, mission objectives, market research reports, etc.
11. *Coordinate arrival of mission party with Foreign Commercial*

Service offices, so that mission participants have their necessary visa papers, documents, product samples, etc. We coordinate with FCS to ensure that the mission is greeted at the airport along with transportation to the hotel.

12. *Perform actual trade mission activities*, coordinating meetings with MOH and industry representatives, keeping each participant fully informed of daily meetings and maximizing their exposure to business contacts. We conduct interviews and determine actual and potential sales that will occur as a result of the mission.

13. *Perform mission follow-up activities*, including thank you letters to all participants and keeping in close contact with the firms.

The following trade missions were made possible by the UHIPP program. They were sponsored by the DOC, and partially funded by UHIPP through USAID.

October 11-19, 1992 U.S.-Russia Health Industry Trade Mission

Twenty-one U.S. medical equipment, pharmaceutical, and health services firms participated in this mission. The delegation visited Moscow and the Tatarstan cities of Kazan, Naberezhney Chelney, and Nizhnekamsk and met with local healthcare officials and business representatives. The mission helped several participating U.S. companies to obtain information on the Russian market for healthcare products and services and to identify significant business opportunities in the region.

June 21-30, 1993 Health Industry Trade Mission/Seminar to Kiev and Lviv, Ukraine

Representatives from 14 U.S. companies in the healthcare services industries participated in this mission, which visited the Ukrainian capital of Kiev, as well as the western Ukrainian city of Lviv. As a result of individual business meetings with their Ukrainian counterparts, five U.S. healthcare services firms were able to develop contacts for future business discussion, secure business orders and, in one case, to announce a joint venture.

October 13-21, 1994 Medical Equipment/Health Services Mission to

Yekaterinburg and Chelyabinsk (Urals Region)

Commerce led 10 U.S. firms to the Urals cities of Yekaterinburg, Chelyabinsk, and Miass. The mission participants had over 350 business meetings with potential Russian business partners. The mission achieved outstanding results with American firms reporting expected sales of \$10 million over the first two years.

June 11-17, 1995 Business Development Mission to Kazakhstan and Uzbekistan

Commerce led 12 U.S. medical equipment, health services and pharmaceutical firms on an eight-day mission to the Central Asian countries of Kazakhstan and Uzbekistan. The mission provided U.S. company representatives the opportunity to meet with regional leaders, public health officials, medical professionals, and potential business partners.

October 11-19, 1995 Medical Business Development Mission to the Russia Far East

Commerce led 16 U.S. medical equipment, pharmaceutical and health services firms to explore the health industry opportunities in Russia's largest region, the Far East, which covers 36% of the country. The mission visited cities of Vladivostok, Yuzhno-Sakhalinsk, and Khabarovsk, and focused on identifying emerging commercial opportunities in the region.

September 17-26, 1996 Medical Mission to St. Petersburg and Siberia

Commerce led 11 firms representing a variety of U.S. medical industry products to the cities of St. Petersburg, Novosibirsk, and Barnaul to meet with government officials, potential customers, and business partners. A new approach was used for this mission, in which the trade mission was developed and organized in concert with the ABC-Novosibirsk. The mission achieved excellent results including: the signing of seven contracts with a total value of \$2 million; numerous future contracts estimated at \$2 to \$10 million; and numerous leads and contacts in the above cities.

October 18-26, 1997 Trade Mission to Nizhny Novgorod and Tatarstan

In cooperation with the Nizhny Novgorod American Business Center, DOC organized a successful trade mission to Nizhny Novgorod and Tatarstan. The trade mission included 145 one-on-one meetings for the five firms in attendance. The mission generated an estimated \$14 Million in long-term sales and estimated \$2.5 Million in short-term sales.

B. Reverse Trade Missions/Conferences

UHIPP sponsored reverse trade missions which brought potential foreign buyer delegations from Russia and the NIS to the U.S. to meet with U.S. company representatives. Much like the trade missions to Russia and the NIS, these missions included group meetings, one-on-one meetings, discussions and other special events between the foreign delegates and U.S. companies.

The following trade missions were made possible by the UHIPP program. They were sponsored by the DOC, and partially funded by UHIPP through USAID.

November 1993 Reverse Trade Mission from St. Petersburg to the National Home Health Care Expo/Medtrade '94 in Atlanta, GA

At the trade show, Commerce arranged meetings and worked with a delegation of Russian government and business representatives from St. Petersburg. Several business relationships with U.S. companies resulted at this trade show.

March 1994 Health Industry Business Roundtable and Reverse Trade Mission from Ukraine to Chicago

A delegation of 24 Ukrainian business and government officials met with over 50 U.S. companies during the four-day event. The purpose of this reverse trade mission and Roundtable conference was to provide an opportunity for members of the Ukrainian delegation to present information about trade opportunities in the Ukraine for medical equipment, pharmaceutical, and health services sector, and to present their ideas for commercial cooperation with U.S. firms. The Ukraine delegation also visited a number of Chicago based medical producers and local hospitals.

November 1994 Biotechnology Industry Reverse Trade Mission from Russia

Commerce organized the first official U.S. government sponsored Russian Reverse Trade Mission on biotechnology. The eight-member Russian delegation included scientists from St. Petersburg and Moscow representing Russia's leading biotechnology institutes. The purpose of the mission was to enhance commercial opportunities for the Russian and American biotechnology industries, including the development and the commercialization of innovative technology related to the healthcare industry. The mission included technical seminars, plant visits, and meetings with over 100 U.S. companies and individuals in Maryland, California, Michigan, and Massachusetts.

June 1995 Reverse Trade and Investment Mission from Ukraine to the 13th Annual Medical Design and Manufacturing Conference and Exposition (MD&M) in New York

Commerce brought a 49 person delegation of Ukrainian government officials and business representatives to New York's MD&M Exposition which is the world's premier event for medical equipment design, components, and materials. The delegation viewed products and technologies of some 750 U.S. manufacturers. Individual delegation members also participated in facility tours and visited healthcare providers, and medical and dental equipment manufacturers, and suppliers in the area.

April 1996 Health Industry Reverse Trade Mission and Conference from the Russia Far East to Seattle, Washington

In cooperation with the Russian-American Foundation for Economic Cooperation, Commerce brought 15 leading healthcare officials and private industry firms from the Russian Far East to Seattle, WA to meet with U.S. medical sector firms and to participate in a conference on health industry opportunities in the region. The core of the mission was a two-day conference on Health Industry Opportunities in the Russia Far East. The reverse trade mission and conference activities were a follow-up to the October 1995 highly successful U.S. Health Industry Business Development Mission to the Russia Far East.

In Seattle, Russian delegation members met one-on-one with U.S. firms, visited medical hospitals, treatment centers, and medical and dental clinics and manufacturers. They also participated in bilateral industry panel discussions.

February 1998 Russia Reverse Trade Mission and Conference, Los Angeles

The Department of Commerce coordinated a two-part event in Los Angeles, February 22-26, 1998: a Russia Medical Reverse Trade Mission, and a Conference held in cooperation with UCLA Medical Center, where representatives from the Russian MOH and GOSSTANDART trained U.S. firms on the procedures for properly registering and certifying medical devices and pharmaceuticals for the Russian market. Panelists representing six regions in Russia also discussed market conditions and opportunities there for U.S. medical firms.

The Russian Delegation consisted of 24 government officials, hospital administrators, and private sector representatives, and represented Nizhny Novgorod, Tatarstan, Novosibirsk, Novgorod, Samara, Togliatti, and Altai Krai. As part of the Reverse Trade Mission, the Delegation had site visits to U.S. manufacturers of medical equipment in Los Angeles and Orange County, resulting in an estimated \$75 Million in long-term sales, and approximately \$2.4 Million estimated for short-term sales. Approximately 70 U.S. firms attended the Conference, and a total of 130 one-on-one meetings were held between U.S. firms and Russian delegates. The entire conference was taped and a transcription was made.

C. Regulatory Roundtables

Regulatory Roundtables have proven to be an excellent means for U.S. firms to better understand the process by which their medical products are registered and certified for the Russian and NIS markets.

The following regulatory roundtable was made possible by the UHIPP program. It was sponsored by the DOC, and partially funded by UHIPP through USAID.

February 1998 Regulatory Roundtable, Los Angeles

The Commerce Department brought representatives from the Russian MOH and GOSSTANDART to train U.S. firms on the procedures for properly registering and certifying medical devices and pharmaceuticals for the Russian market. Panelists representing six regions in Russia also discussed market conditions and opportunities there for U.S. medical firms.

June 1998 Regulatory Roundtable, Moscow

The Department of Commerce, in cooperation with the AmCham Moscow Health Committee, the Russian MOH, and GOSSTANDART, held a Regulatory Roundtable on medical devices on June 16, 1998 in Moscow. Topics of discussion included importing, licensing, and certification of medical equipment in Russia. Approximately 60 U.S. firms attended the event. The Roundtable successfully completed one of the activities of the Health Industries Subgroup's Workplan. AmCham Moscow organized an impressive panel of speakers including representatives from the Russian MOH, GOSSTANDART, and the Russian Duma. The DOC arranged for the Roundtable's simultaneous translation and had a transcript created for distribution.

D. BDC Activities and Accomplishments

Another element in the UHIPP program was its support of the U.S.-Russia Business Development Committee (BDC) Medical Equipment, Pharmaceuticals, and Health Services Subgroup. The Health Industry BDC Subgroup's purpose is to identify and seek removal of obstacles to U.S.-Russian trade and investment in the medical product and healthcare service industries, and to assist U.S. and Russian companies in identifying prospects for commercial cooperation. The Subgroup has attempted to reduce regulatory barriers to trade and has supported business missions and other trade promotion activities between the U.S. and Russia.

Since its inception in October 1992, the Subgroup has met seven times:

1. Winter 1993, San Diego

2. Fall 1993, Moscow
3. Spring 1994, U.S.
4. Fall 1994, Moscow
5. Spring 1996, Moscow
6. Summer 1997, Moscow
7. June 1998, Moscow

Some of the major accomplishments of the BDC Health Industries Subgroup have been the Pharmaceutical MOU, the Medical Device Brochure, and the tracking of various joint-venture projects.

The following is a summary of the Russian perspective of the status of the projects given at the most recent (June 1998) BDC Subgroup meeting.

Searle - Construction of the Searle plant is nearly complete. Some changes have taken place in the company, but the plant is on schedule. It will be commissioned in 1999. Some problems have arisen, but there appears to be no danger of delaying the 1999 opening.

Bristol-Myers, Squibb - Production of one product has doubled since 1996-1997 and production of a second product has begun. A new packaging facility has been built and is in operation. It is packaging two new products.

MIR - The Russian delegation stated its belief that the MIR project had been abandoned, as they had no evidence of activity. The U.S. side remarked that MIR has reported the importation into Russia of a substantial quantity of pharmaceuticals, and that engineering plans to convert an existing building had been completed. Further, AID support for the project has not been terminated, and the BDC is obligated to support the project as long as it is in development. The U.S. side committed to obtaining information to clarify the status of this project and report back to the Russian MOH.

Certification Laboratory - All the preliminary paperwork has been completed, the feasibility study and design work are finished. All necessary approvals from the various ministries have been obtained. However, expected Ex-Im Bank loans will not be granted until sovereign guarantees are received from the GOR. Unfortunately, there is a Presidential moratorium on foreign loans, so the needed guarantees are not being pursued at this time. Application will be made for the sovereign guarantee as soon as the

moratorium is lifted. The Russian delegation expressed that the support of the BDC has been instrumental in the advancement of this project.

State-of-the-Art Drug Stores - The project has been delayed by the absence of a regulatory basis for the bar code system the stores intend to use for the pharmaceuticals. Technical development has been successful, but the system cannot be implemented yet. The U.S. side expressed concern that aside from the bar code problem, the project has been delayed for more than a year due to loss of the original site for the first store. The U.S. delegation called on the Russian delegation to help resolve the impasse in obtaining an alternative site, so that equipment, currently in storage, can be installed.

Plant for Blood Products - This project was deemed to be very important to the Russian Federation. The U.S. side reported that the delays in obtaining financing have discouraged the U.S. partner in this project and that the firm has asked for a letter indicating the commitment of the Russian Federation. The GOR was said to have prepared many documents for the project already and is willing to provide whatever is needed to continue the project. The DOC representatives committed to follow-up with the U.S. partner to determine exactly what is needed.

Sharing Technology - The U.S. delegation noted the omission of this project from the Russian report. The Russian side stated that this is one of many projects underway to bring Russian and American medical professionals together to share information, and that the BDC should discontinue its monitoring. The U.S. cited the agreement to monitor this particular project to help ensure its success and that it had the backing of the prestigious American College of Physicians. Further, the program's director was currently in Russia to make contacts for upcoming events.

E. Ad Hoc Work Group

The GCC Health Committee Ad Hoc Work Group on Trade and Investment

At the June 28, 1995 meeting in Moscow, the Gore-Chernomyrdin Health Committee formed the Ad Hoc Work Group on Trade and Investment Issues. As stated in the Ad Hoc Work Group's Report and Recommendations, "the Work Group was formed to help increase the availability in Russia of

critically needed pharmaceuticals, medical devices, dental devices, and supplies, and to encourage greater collaboration between U.S. and Russian firms in that process.” A glaring need to facilitate trade and investment in the Russian healthcare community was a main priority noted by the Work Group. The U.S.-Russia Business Development Committee's (BDC) Subgroup on Medical Equipment, Pharmaceuticals, and Health Services, created by the Gore-Chernomyrdin Commission, was created to identify and seek the resolution of trade barriers and other obstacles to the U.S.-Russia commercial relationship.

The U.S. contingent of the Work Group is Co-chaired by U.S. Department of Commerce Deputy Assistant Secretary Michael Copps, and Food and Drug Administration Deputy Commissioner Mary Pendergast. Representatives from the U.S. Department of Commerce, Health and Human Services, State, the Overseas Private Investment Corporation, the Agency for International Development, and the U.S. Trade and Development Agency are also affiliated with the Work Group. The Russian delegation was chaired by Alexei Vilken, Deputy Minister of Health and Medical Industry. Other members of the Russian delegation are represented by the Office of the Government of

the Russian Federation, the Ministry of Health and Medical Industry of the Russian Federation, the Ministry of Economy, the Ministry of Foreign Economic Relations, and the Ministry of Finance.

The Work Group issued its final report in Winter 1996, which concluded the activity of the Work Group. The Work Group report also established the U.S.-Russia Health Industries Subgroup as the entity to implement trade and investment activities. At each GCC Health Committee Meeting, the U.S. and Russia BDC Co-Chairs present a report on trade and investment.

What UHIPP Taught Us

Challenges and Strategies for U.S. Medical Firms in Russia

Over the last six years of the UHIPP program, the Department of Commerce has been able to work closely with U.S. firms to gauge the problems and challenges facing them in the Russia and NIS markets. One of the goals of the UHIPP program was exposing U.S. firms to these infant economies and to gather much needed market intelligence. The following comments are examples of the intelligence gathered on these markets. Note: they were gathered before the financial collapse.

In general, firms felt that the long-term business outlook in Russia was good, and had made a commitment to stay in the market. However, considerable short-term problems were noted. In addition to difficulties associated with currency convertibility and the instability of tax and legal regimes which affect all firms doing business in Russia, company officials reported obstacles including lack of support from both the Ministry of Health and the Health Care Department of the Russian Federation, unreliable and corrupt distribution networks, an arbitrary, opaque, and slow regulatory system for medical products, a lack of sophistication among consumers and medical professionals, payments arrears owed their firms, inadequate U.S. government support, and risk-aversion from their headquarters.

A. Lack of Support from Central Russian Health Authorities

(Most company representatives used the term “Ministry of Health” generically, and did not distinguish between the Ministry and the Health Care Department of the Russian Federation).

1. The central health care authorities are considered an obstacle by most firms, who believe it best to avoid these authorities when possible, and to deal instead with regional or local governmental units, hospitals, enterprises, and other end-users. Firms perceive that the central health authorities' influence is only negative, i.e., they can obstruct projects which are not in their favor, but are not able to advance projects which they support.
2. Companies believe that the MOH are not concentrating on what needs to be done in developing Russia's health care policy. It seems to most companies that they are only interested in putting together deals over which

they retain a share of operational and financial control, and are not focusing on vital health policy issues. Compounding this problem is the fact that there have been several different Ministers of Health, and this leadership turnover has made it difficult to ascertain whom to deal with, much less to establish smooth relationships.

3. According to company representatives, federation-level health and finance officials do not understand that for a U.S. firm to establish manufacturing operations in Russia requires good prospects for a profit. One pharmaceutical firm estimated that it would take up to 20 years to recover its planned investment, provided it could sell its output at world prices. Financial concepts such as opportunity cost and time-value of money, which are crucial to investment decisions, seem lost on senior Russian health officials.

4. Sales to the MOH through its procurement budget have declined dramatically over the past two years. To the extent that a centralized health procurement process still exists, it is kept too much of a secret. According to U.S. firms, there is no semblance of an open, competitive bidding mechanism.

5. Most company officials' comments supported the view that domestic manufacturers get strong preference with the Russian government, even in cases where their products are markedly inferior. On the other hand, some firms asserted that even in cases where Russian products are comparable in quality to Western or Asian products, and increasingly where the purchaser is an individual or an enterprise (as opposed to a government entity), "made in Russia" is a stigma, and foreign products are preferred.

B. Distribution of Drugs, Equipment, and Supplies

1. Some companies complained that even though they sold product to the MOH for a low price, the price ultimately charged to the Russian consumer was significantly escalated, often ten to 15 times higher. Under these conditions, there is no incentive to keep prices low, since the middlemen will raise the price to the maximum extent the market will bear. As a result, Russian consumers are not able to purchase as many drugs or devices as they would if they received the full benefit of the subsidy, and U.S. firms are often blamed for the highest prices at which their products appear on Russian markets, when in reality individuals in the distribution system are to blame. In the view of U.S. firms, it would be better to provide the 80% subsidy directly to consumers or to healthcare providers rather than through the MOH.

C. Certification and Approval for Drugs and Medical Devices

1. U.S. medical firms complained that Russian government officials view

drug and medical device regulation foremost as a source of revenue, a “cash cow” as one company representative put it. Firms feel that the process for certifying and registering drugs and devices in Russia needs to be more consistent, with uniform treatment and standards for all companies, more transparent, and more expeditious. One of the major breakthroughs in this area is the publication of the Medical Device Brochure in June 1998, which allows U.S. firms for the first time to know exactly what they are required to do to properly register and certify their products for the Russian market.

2. Rather than uniform, one-time application and registration fees, some firms report they have been asked to pay a percentage of revenues from their Russian sales to expedite product approvals. In some cases, approvals are subject to “renewal,” requiring additional fees.

3. Company representatives also maintained that even in cases where requirements are fairly transparent, the approval process is exceedingly slow compared with those of Western regulatory agencies. U.S. company officials indicated that non-U.S. firms which are willing to bribe Russian officials tend to receive approvals more expeditiously (Indian, Yugoslavian, and Italian firms were implicated by several companies' representatives).

4. Company officials whose firms are members of the International Pharmaceutical Manufacturers Association report that some European pharmaceutical firms are experiencing similar problems in Russia.

5. Ideally, U.S. firms would like to see a system established wherein if a drug or medical device receives approval from the U.S. FDA, no further Russian approval would be necessary. However, several U.S. firms granted that this was an unrealistic goal, as Russia is likely to maintain its own regime of drug and medical device regulation for both public health and financial reasons. One company official even pointed out that, as conditions in Russian hospitals are very different from those in the West, it would not make good medical sense for Russian hospitals on the basis of clinical trials performed under U.S. clinical conditions.

D. Lack of Sophistication on the Part of Russian End-Users

1. Lack of knowledge on the part of healthcare professionals was also cited as a problem. Doctors and nurses appear to have been trained inadequately,

if at all, in use of many types of medical equipment which are standard in the West. Russian hospitals often seek to purchase expensive, state-of-the-art equipment such as CT scanners and magnetic resonance imaging (MRI) units, partly for reasons of prestige, although their staffers are generally capable of using and maintaining only 10-15% of such advanced technology correctly.

2. Lack of respect and appreciation for Good Manufacturing Practices (GMP) standards and intellectual property rights were frequently cited as problems, especially where purchase of pharmaceuticals is concerned. U.S. drug firms complained of “pirated” drugs being imported from India and the former Yugoslavia. Although these drugs are of questionable quality, according to U.S. firms, they are attractive to Russian buyers simply for their lower cost.

E. Payments Arrears Owed to U.S. Firms

1. Many of the U.S. medical equipment and pharmaceutical firms with whom we met underscored that unresolved debts owed to them by Soviet-era organizations or their successors, as well as by more recently-created Russian organizations, are preventing their headquarters from committing greater resources to developing business in Russia, through either sales or investment. This problem has become even more acute since the recent Russian financial collapse.

F. Lack of U.S. Government Support

1. Up until the recent financial collapse of Russia, when asked about U.S. government support, nearly all firms, unsolicited, responded that the need for food aid in Russia is vastly overstated relative to the need for upgrading the state of healthcare. The companies expressed regret that U.S. export assistance to date has been, for the most part, limited to agricultural products. Representatives of several large companies considering investments in Russian production operations expressed the view that some sort of short- or medium-term payment guarantees which the Russian government has been unwilling or unable to provide - - could be decisive in moving some of their investment plans forward.

2. Several U.S. firms reported that they have sourced exports to Russia from their European subsidiaries, rather than from their U.S. production operations, in order to take advantage of HERMES and other assistance offered by EC

countries to their exporters.

G. Lack of Initiative from U.S. Companies

1. Representatives of several companies which have been selling for hard currency in Russia confided that they would be able to do greater short-term business if they received greater support from headquarters. According to these representatives, general political instability and, in some cases, payments arrears on past contracts make arguing for greater resources for Russian operations a “tough sell” with company management.
2. Some companies stressed that U.S. healthcare firms generally need to be more willing to donate equipment and other products, and to provide free training to Russian medical professionals. Although such actions have the drawback of tightening the current market for sales, they provide goodwill and company name recognition that will be invaluable in a long-term strategy to develop the Russian market.

H. Taxes and High Start-Up Costs

1. In theory, Russia's tax regime offers tax advantages to foreign investors. However, in practice the uncertain duration of tax advantages engendered by frequent fluctuations and retroactive changes in the Russian tax code have the same negative impact on potential investors in other industries. In fact, the medical industry requires special incentives given the low potential for profits in the medical equipment and pharmaceutical industries in Russia relative to, for example, energy development or telecommunications.
2. U.S. firms also have difficulty in getting up-to-date information regarding laws and regulation. Russia publishes new documents unbeknownst to U.S. companies.

I. Uncertain Availability of Raw Materials

1. Uncertain availability of raw materials, particularly those which must be imported from abroad, is a main concern of U.S. firms. The need for extensive cleanup of environmental damage at some potential investment sites pose obstacles to investors in the medical industry as well, given the industries unique requirements for high-quality water, material, chemical and

other inputs.

J. Tariffs

1. Russia has threatened to raise tariffs from 10% to 70-100% on imported medical devices and pharmaceuticals to protect Russia's medical industry. The Russian medical industry is uncompetitive and lacks modern technology compared to the rest of the world. The proposed tariff increase could have a negative impact on the overall availability of U.S. pharmaceuticals in the Russian market which could lead to increased smuggling. In addition, this type of protectionism of Russia's domestic industry can be counterproductive to the government's goal of creating a more competitive environment among domestic producers.

K. Political Instability

The political climate in Russia and the NIS region is well documented. The political instability is a major concern for U.S. firms especially in terms of investment.

L. Different Perception Between U.S. Firms and Russian Government of Trade and Investment in Russia

Many U.S. firms perceive investment in Russia as too risky due to the factors mentioned in this section of the report. On the other hand, Russia sees the cautiousness of U.S. firms as unwillingness by U.S. firms to invest in Russia which leads to Russia's government leaders making policies and laws that are uncooperative.

M. Intellectual Property Right Protection

1. The area of intellectual property rights is especially critical to U.S. pharmaceutical and medical device companies which annually invest, on average, more than 10% of their revenues, nearly triple the average American industry as a whole, on new product development. While reports of actual infringement on intellectual property by Russian organizations have been rare, Western-style intellectual property protection has only a brief history in Russia which has led to caution among some American investors considering possible investments with Russian partners.

What U.S. Firms Need to Know

Today, in large part due to UHIPP activities, there are many more opportunities for U.S. health industry firms in Russia and the NIS than several years ago. However, the risks involved should not be ignored when conducting business in this region.

1. U.S. firms will have to think of imaginative and flexible ways to successfully adapt to business practices that can vary widely from deal to deal.
2. U.S. firms have to emphasize after-sale services, long term payment plans, offer equipment on trial basis, step up marketing, etc.
3. It is important to choose a reliable business partner. There is a trend toward dealing with regional and local authorities, private enterprise, and away from central control. U.S. firms will have to go directly to end-users.
4. In international trade, U.S. firms are committed to upholding the Foreign Corrupt Practices Act, despite the many temptations in the Russian market to do otherwise. Unfortunately, for their commitment to conducting their business in a legal and honest manner, many U.S. firms have lost contracts to foreign competitors who are willing to accept bribes and other illegal activity. U.S. firms must not under any circumstances take the easy way out and conduct business illegally.
5. These countries are looking for business deals that help them establish manufacturing capacity.

6. Trade and investment may take many different forms, such as direct sales to firms, distributors, joint ventures, co-production, barter/counter-trade, sale in rubles with convertibility, etc.

7. Although there are limited funds in this region, there are pockets of opportunities in oil rich areas with some control of oil revenues, mineral rich areas, and cities with large factories.

Where We Go From Here

“The UHIPP program has made a dramatic impact on U.S. firm access to the emerging markets of the NIS. The U.S. government must continue these efforts if we want to accomplish our goals in this region.”

Susanne Lotarski, Director, Office of Eastern Europe, Russia, and the Independent States, U.S. Department of Commerce

Since the close of the UHIPP program, Russia has experienced a financial collapse, affecting to an extreme degree its citizens and those of its trading partners, the NIS. *Now more than ever, the quality of healthcare in this region depends on the collaboration between U.S. government and industry.* With sustained effort, the U.S. government and U.S. industry can help Russia and the NIS move in the right direction. Continued collaboration means continued emphasis on improvements to the regulatory regime and business environment. Continued collaboration means market access for U.S. exports, and citizen access to the most basic sterile medical supplies to the highest quality surgical equipment in the world. To stop the regulatory and cooperative activities now risks negating six years of stirring change in Russia and the NIS.

While administratively the UHIPP program has come to a close, the needs are still there. Clearly this region is still in development. The UHIPP program helped Russia and the NIS chart a course toward improved regulations in registering and certifying medical devices and pharmaceuticals, and improved delivery of crucially needed medicines and equipment to their citizens.

On the Brink of Real Improvements

Fiscal Year 1998 is not simply the year of the financial collapse. *Fiscal Year 1998 was a year of tremendous breakthroughs and outcomes from UHIPP sponsored activities.* DOC is hovering on the brink of making never before strides in our partnership with the NIS in improving the business and regulatory environments for the health sector. The following is a sample of the breakthroughs made in FY 1998 alone thanks to the UHIPP program:

Publication of the Medical Device Brochure, June 1998.

This is a document that U.S. Exporters have been waiting for, and thanks to UHIPP funds, it is now a reality. For the first time, U.S. exporters know step-by-step what it is exactly they need to do to get their product registered and certified by the Russian Federation. The Brochure is a breakdown of a major non-tariff trade barrier for U.S. firms.

Two Regulatory Roundtables, February and June 1998.

In an example of bilateral cooperation, dignitaries from GOSSTANDART and the Ministry of Health participated in Regulatory Roundtables both in Los Angeles and in Moscow.

Negotiations with the Government of Ukraine for a Cooperative Agreement.

The U.S. has drawn up a Statement of Intent with the Government of Ukraine that spells out practical ways the two governments will work together to improve the regulatory and business environment for the health sector in Ukraine. Negotiations have taken place in Kiev in June 1998, in Washington in August and October 1998. The Ukrainians have given word they are ready to sign the document.

What the Future Could Hold if Funded

The International Trade Administration has ambitious goals for Fiscal year 1999. USAID funding for continued development in this region is needed to make these goals realistically attainable. *If funded, OMMI would in FY 1999:*

Make Significant Improvements with Ukraine.

The bilateral agreement is already in place. The steps are outlined. With funding, the way is clear. The result would be a systemized approach for U.S. medical manufacturers to know exactly what the procedures are for getting products registered and certified in Ukraine, and more importantly, the agreement calls for U.S. industry and U.S. government to work with Ukraine to improve their existing procedures. ***The result:** an improvement in access to quality health care devices and medicines and increased U.S. trade and investment in Ukraine.*

Create an Information Clearinghouse for Russian Trade Opportunities.

Russian medical tenders are common, just not common knowledge to U.S. exporters. This clearinghouse would be a cooperative effort between Russia and the U.S. Department of Commerce to get Russian medical tenders out to a centralized location where U.S. exporters can learn of the opportunities that are still coming from regions with natural resources and ability to pay. ***The result:** increased access to high quality medical product to Russian citizens, increased U.S. exports, and an increase in high-wage, high-skill jobs in the U.S.*

Provide a SABIT Training Program for Russian Hospital Administrators.

U.S. exporters are making themselves clear: Russian hospital administrators are responsible for purchasing medical equipment, but they do not yet have the skill set needed to make intelligent planning and purchasing decisions. Modern principles of accounting are necessary for these positions. U.S. hospital administrators have the training and the skills, and are eager to teach the Russian and other NIS administrators. ***The result:** increased efficiency and better resource allocation for NIS hospitals; increased U.S. exports.*

Identify and Work to Eliminate the Reasons for the High Cost of Medicine in the NIS.

The draft report has been submitted to the Duma, outlining what the U.S. sees as the underlying reasons for the outrageous prices of high-quality medicines from the U.S. Working together and supported by UHIPP funding, the two governments will strive to remove these causes. ***The result:** increased access to high-quality U.S. medicines for Russian and NIS citizens, increased U.S. exports of pharmaceuticals.*

Lead a Health Industries Trade Mission to Ukraine, 1999.

With our negotiations with Ukraine coming to bear fruit, we will need to in good faith lead a health industries trade mission to Ukraine in 1999. Given the financial collapse of Russia, it may not be feasible to expect U.S. companies to absorb all the financial risk of the trade mission and market intelligence gathering in order to provide Ukraine with better quality medical devices. This trade mission would be the first ever in Ukraine to occur after U.S. firms would have set down in one place everything they need to know in order to bring their product to the Ukraine market. In order to lead this trade mission, OMMI believes that UHIPP funding would be necessary. ***The result:** increased commitment and cooperation on behalf of the Ukraine*

government, increased market intelligence and exposure for U.S. medical firms.

Hold a Russia Customs Regulatory Roundtable.

Our working relationship with the Russian Ministry of Health and GOSSTANDART is no longer in question. Ensuring cooperation from the Russian Customs is now extremely important and is one of the last pieces of the puzzle. U.S. exporters have made themselves heard by the Russian Ministry of Health: “we follow your rules, but Customs doesn't use the same rules you do. Our high-technology devices and pharmaceuticals sit on the docks for months.” The Russian Ministry of Health has acknowledged the miscommunication and is now willing to work with the U.S. government and Russian Customs to ensure the same rules apply across the agencies. Momentum is behind this effort. Stopping now will certainly mean an end to the process. Working with Russian Customs will require funding. ***The result:** U.S. exporters of health products will follow one set of rules and have their products into the country unimpeded, Russian citizens will have access to fresh and not outdated medicines.*

Continue Dialogue with Russian Health Officials through the U.S.-Russia Health Industries BDC Subgroup.

Conclusion

The six year UHIPP program has been a major success in terms of export promotion, intelligence gathering, and regulatory improvement. Attached as Appendix A is a third party review of the impact of the UHIPP program on participating U.S. firms and on the Russian health care. The Department of Commerce will continue to work in this region without USAID funding, and USAID funding would significantly add to its capabilities.

1. One participant on the Russian Far East Mission stated, “The trip was very valuable, because it gave us information we did not have before. As a result, we continue to monitor the situation and hope someday to put together some business. . . We did not expect to make any immediate sales. We did expect to learn a lot. Our expectations were met.”

2.UHIPP activities such as trade missions, reverse trade missions/conferences, and policy work to reduce trade barriers strongly contributed to expanding U.S. medical exports to Russia from \$15 million in 1992 to almost six times that amount, \$87 million, in 1997. U.S. medical exports to the NIS grew almost in the same proportion from \$22 million in 1992 to \$98 million in 1997.

3.A firm reported on its site visit by the Russian Delegation on the Russia Reverse Trade Mission in Los Angeles, “During the visit we had very constructive discussions with the Russians and got information that is vital for our business. We shared with them our every day experience and our problems with exporting and registering American products to Russia. The discussion was very efficient and will bring mutual benefits for American manufacturers and the Russian Health Care sector. . . it was an extremely useful event.”